AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Serial Number: 10/003,853

Filing Date: November 2, 2001

Title: NOVEL IONTOPHORETIC DRUG DELIVERY SYSTEMS

Page 10 Docket No.: 0434-4729US

REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on March 23, 2006, and the references cited therewith. In the Office Action, claims 1-21 and 23-37 were examined. Claims 1-21, 23, 25-35, and 37 were rejected. Claims 22 and 38 were previously cancelled. Claims 24 and 36 were objected to.

Claims 1-38 have been cancelled. New claims 39-76 have been added. Of the new claims, claims 40-47 correspond to previously presented or original claims 2-9. Claims 49-50 correspond to original claims 11-12. Claim 52 corresponds to original claim 14. Claims 54-56 correspond to original claims 15-17. Claims 59-61 correspond to original claims 19-21. Claims 62-65 correspond to original claims 23-26. Claims 68-76 correspond to previously presented or original claims 28-37. These new claims do not contain new matter. New claims 39, 48, 51, 53, 57, 58, 66, and 67 also do not contain new matter

102 Rejection of the Claims

Claims 1-11, 13, 17-21, 23, and 25-35 were rejected under 35 USC §102(b) as being anticipated by Roberts, et al., (U.S. Patent No.: 6,01,088, hereinafter "Roberts"). As the Examiner is aware, in order for a reference to properly anticipate a claim under 35 U.S.C. §102(b), "each and every element as set forth in the claim [must be] found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987), cited in MPEP §2131. Applicant asserts that each and every element of claims 39-78 are not taught by Roberts, and thus respectfully requests the withdrawal of this rejection.

Independent claim 39 states that the first and second electrodes of the device comprise electropositive and electronegative material respectively. See, e.g., claim 39 supra. This claim element is supported in paragraphs 39, 40, and 71. Applicant has previously noted that the Roberts reference fails to teach the use of electropositive or electronegative materials and hereby incorporates its earlier responses herein by reference. Examiner has previously asserted the "that the metal electrodes are inherently electropositive and electronegative". Applicant, however, claims that its combination of electropositive material, electronegative material, conductor, and ionic fluid form a battery. Roberts does not teach this. Applicant asks Examiner to take notice

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

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Page 11 Docket No.: 0434-4729US

of the fact that not every pair of metals, absent the power source taught be Roberts, acts as a battery when coupled to a conductor and ionic fluid. For example, there are metals that inherently retain or yield their valence electrons absent an additional electromotive force. Using two metals that tend to retain their electrons or two metals that tend to lose their electrons will not create an electromotive force. Simply placing two metal electrodes of the type taught in Roberts in connection with a conductor and ionic fluid will not form a battery. In fact by requiring a power source, Roberts teaches away from the use of an electro positive electrode and an electro negative electrode that form a battery *absent* an additional power source. Claim 53 states that the first and second electrode are configured as part of the same housing. This claim is supported by Figures 2 and 3. Roberts teaches two probes or electrodes that are positioned separately. Applicant's device contemplates a unitary device where both electrodes are implanted beneath the skin. See Figures 2-4. Roberts does not teach a unitary housing containing both electrodes.

Claim 57 states that an ion exchange member configured to conduct a current is required in Applicant's electrotransport device. This claim limitation is supported in paragraphs 53 and 63 of Applicant's application. Roberts does not teach an ion exchange member configured to conduct a current. Roberts mentions a dialysis membrane. Dialysis works on the principle of diffusion of solutes along a concentration gradient. See http://www.answers.com/dialysis, incorporated herein by reference. Dialysis membranes separate smaller molecules from larger molecules. Applicant teaches an ion exchange membrane where ions exchange that works under electrical current or potential, not concentration gradients. Accordingly, Roberts does not teach the limitations of claim 57.

Claim 58 states that a pair of electrodes are positioned a fixed distance from each other. This claim limitation is supported in Figures 2 and 3. Roberts teaches two probes or electrodes. See Roberts Figures 3A-3C. Roberts teaches the independent placement of two separate electrodes. Applicant teaches the implanting of both electrodes as part of a single device. The device in some embodiments fixes the electrodes at a certain distance from each other. Roberts teaches away from this concept.

Docket No.: 0434-4729US

Claim 66 teaches the use of electropositive and electronegative material for its electrodes and for the reasons set forth above in connection with the Claim 39 discussion, Roberts does not anticipate claim 66.

Claim 67 teaches a method step where both the electrodes and the membrane are implanted in their entirety beneath the subject's stratum corneum skin layer. This limitation is supports by Figures 2 and 3 of Applicant's application. Applicant's device is wholly implantable. Roberts' device cannot be wholly implantable. Thus, Roberts teaches away from implanting the entire device.

Claim 74, similar to claim 39, teaches the use of complementary electropositive and electronegative electrodes that form a battery absent an additional power source. For the reasons that claim 39 is not anticipated by Roberts, neither is claim 74.

Roberts fails to teach each and every element of Applicant's independent claims.

Accordingly, Roberts fails to anticipate all the claims of the instant application, and Applicant respectfully requests the withdrawal of this rejection.

103 Rejection of the Claims

Claim 12 was rejected under 35 USC §103(a) as being unpatentable over Roberts in view of Haak et al., (U.S. Patent No.: 5,445,606, hereinafter "Haak"). Claims 14-16 and 37 were rejected under 35 USC §103(a) as being unpatentable over Roberts in view of Theeuwes et al., (E.P. 0 931 564, hereinafter "Theeuwes"). As with 35 U.S.C. §102 rejections, rejections under 35 U.S.C. §103(a) must teach each and every element of the claims. Since Roberts itself fails to teach each and every element of claims 1 and 35 from which rejected claims 12, 14-16, and 37 depend, and since Haak and Theeuwes were cited for their teachings of control circuits and carbon electrodes, respectfully, Applicant asserts that this rejection is unsupported and respectfully requests its withdrawal.

Conclusion

Title: NOVEL IONTOPHORETIC DRUG DELIVERY SYSTEMS

Page 13 Docket No.: 0434-4729US

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. As Examiner is aware, Applicant has scheduled an in person interview on May 31, 2006 to further discuss the application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 50-3586

Respectfully submitted,

By their Representatives,

Date May 23, 2006

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<u>CERTIFICATE UNDER 37 CFR 1.8:</u> The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this **23** day of <u>May, 2006</u>.

DAVID FENDA

Name

Signature